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Substitute for form 1449A/PTC

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

**Complete if Known**

Application Number	10/664,803
Filing Date	September 19, 2003
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-424

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code* (if known)	MM/YY		
AA	us	3,174,901	03-23-1965	Sterne	
AB	us	3,960,949	06-01-1976	Ahrns et al.	
AC	us	4,166,800	09-04-1979	Fong	
AD	us	4,389,330	06-21-1983	Tice et al.	
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AF	us	4,839,177	06-13-1989	Colombo et al.	
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AK	us	5,376,771	12-27-1994	Roy	
AL	us	5,478,852	12-26-1995	Olefsky et al.	
AM	us	5,602,133	02-11-1997	Antonucci et al.	
AN	us	5,658,474	08-19-1997	Geerke	
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AT	us	5,952,356	09-14-1999	Ikedu et al.	

**FOREIGN PATENT DOCUMENTS**

[illegible]

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Signature

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Substitute for form 1449A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Art Unit	
		Examiner Name	
Sheet 2 of 5	Attorney Docket Number	141-424	

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AU	US-5,955,106	09-21-1999	Moeckel et al.	
	AV	US-6,011,049	01-04-2000	Whitcomb	
	AW	US-6,031,004	02-29-2000	Timmins et al.	
	AX	US-6,099,859	08-08-2000	Cheng et al.	
	AY	US-6,153,632	11-28-2000	Rieveley	
	AZ	US-6,191,162	02-20-2001	Byrd et al.	
	BA	US-6,248,363	06-19-2001	Patel et al.	
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	BC	US-6,296,874	10-02-2001	Cytie et al.	
	BD	US-6,329,403	12-11-2001	Odaka et al.	
	BE	US-6,383,471	05-07-2002	Chen et al.	
	BF	US-6,403,121	06-11-2002	Adjei et al.	
	BG	US-2002/0071866	06-13-2002	Geerke	
	BH	US-6,451,342	09-17-2002	Adjei et al.	
	BI	US-6,475,521	11-05-2002	Timmins et al.	
	BJ	US-6,524,621	02-25-2003	Adjei et al.	
	BK	US-2003/0113371	06-19-2003	Dhawan et al.	
	BL	US-2003/0118647	06-26-2003	Seth	
	BM	US-2003/0118649	06-26-2003	Gao et al.	
	BN	US-6,599,284	07-29-2003	Faour	

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Examiner Initials	Cite No.	Foreign Patent Document Country Code <sup>1</sup> - Number <sup>1</sup> - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	CA	WO 96/09823	04-04-1996	Luo et al.	
	CB	WO 98/11879	03-26-1998	Shell et al.	
	CC	WO 98/55107	12-10-1998	Shell et al.	
	CD	WO 99/47128	09-23-1999	Timmins et al.	
	CE	WO 99/55320	11-04-1999	Nishii et al.	
	CF	WO 00/28989	05-25-2000	Lewis et al.	
	CG	WO 00/72827	12-07-2000	Straub et al.	
	CH	WO 01/35940	05-25-2001	Lewis et al.	
	CI	WO 01/35941	05-25-2001	Lilliot et al.	
	CJ	WO 01/82875	11-08-2001	Cutie et al.	

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**Compleat if Known**

Application Number	10/664,803
Filing Date	September 19, 2003
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-424

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	y8
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)	MM-DD-YYYY			
	CK	WO 02/28181	04-11-2002	Gidwani et al.		
	CL	WO 03/004009	01-16-2003	Matharu et al.		
	CM	WO 03/035029	05-01-2003	Louie-Helm et al.		
	CN	WO 03/047529	06-12-2003	Seth et al.		
	CO	EP 0 169 455	01-22-1986	Zentgraf et al.		
	CO	EP 0 283 369	09-21-1988	Wiernsperger et al.		
	CO	EP 0 381 181	08-08-1995	Wenzel et al.		
	CR	EP 0 749 751	12-27-1996	Ikedo et al.		
	CS	EP 0 753 298	11-21-2001	Tsujita et al.		
	CT	EP 0 781 129	07-02-2003	Moeckel et al.		

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Substitute for form 1449B/PTO		<b>Compl t if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b>	10/664,803
		<b>Filing Date</b>	September 19, 2003
		<b>First Named Inventor</b>	Unchalee Kositprapa
		<b>Group Art Unit</b>	
		<b>Examiner Name</b>	
<b>Sheet</b> 4	<b>of</b> 5	<b>Attorney Docket Number</b>	141-424

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.	
	DB	P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving-tablet, and three-sustained-release-products", Vol. 24, No. 4 - 1986, pp. 213-220.	
	DC	Finnish Monograph of the Diformin®, Retard tablet, with English translation 2001	
	DD	O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.	
	DE	G. Belcher and D.R. Matthews Experiment and Clinical Endocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.	
	DF	Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.	
	DG	National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.	
	DH	The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).	

<b>Examiner Signature</b>	<b>Date Considered</b>
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Sheet	5	of	5
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Application Number	10/664,803
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First Named Inventor	Unchalee Kositprapa
Group Art Unit	
Examiner Name	
Attorney Docket Number	141-424

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	DI	Product Labeling for Glucophage® XR (July 2002).	
	DJ	ADA Professional Section Member Supplement 047 and 0503-506 (Poster) p. A110; A117 June 1999.	
	DK	Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999.	
	DL	ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175	
	DM	Rote Liste No. 11081 the Medicament Mediabet of MEDICE, Chem.-Pharm. Fabrik Pütter GmbH & Co. KG, Kuhlweg 37-39 Iserlohn/Germany, Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	

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